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09/216,242	12/18/1998	JOHN M. LIPARI	6439.US.O1	1025

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EXAMINER

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ART UNIT	PAPER NUMBER
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/216,242
Filing Date: December 18, 1998
Appellant(s): LIPARI ET AL.

Paper No. 36

*mailed out
date 12.3-03*

Martin L. Katz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9-2-03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Upon consideration, the 102 rejection has been withdrawn.

(7) *Grouping of Claims*

Claims 1, 3, 12, 14, 15 and 16 are grouped together.

Claims 4 and 5 are grouped together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,871,768	BISTRIAN	10-1989
4,952,606	BABAYAN	8-1990
5,645,856	LACY	7-1997
5,753,255	CHAVKIN	5-1998
5,506,230	KIKUCHI	4-1996

Hyltander, A. "Metabolic Effects of Structured Triglycerides in Humans" NCP, vol. 10, No. 3, June 1995, pp. 91-97.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 3-5, 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy (5,645,856), further in view of Babayan (4,952,606), Bistraian (4,871,768), Hyltander (NCP, 1995) individually or in combination.

Lacy discloses capsules containing solutions of fenofibrate. The solutions contain a triglyceride (structured lipid), polyglycerol esters of fatty acids (surfactant) and a cosolvent; the composition contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7). Lacy does not explicitly disclose that the triglycerides are structured lipids. Lacy does not also teach the omission of a surfactant. However, in the absence of showing unexpected results, it is deemed

obvious to one of ordinary skill in the art not to include a surfactant if it is deemed to be not necessary.

Babayan teaches that structured lipids do not elevate cholesterol levels when administered (col. 1, lines 43-50).

Bistraian teaches that structured lipids assist in fighting atherosclerotic problems (col. 3, line 64 through col. 4, line 15).

Hyltander discusses the advantages of the structured lipids and emulsions containing these in clinical practice (pages 92-96).

Assuming that Lacy's triglycerides are not structured lipids, it is deemed obvious to one of ordinary skill in the art to use the structured triglycerides instead of the triglycerides taught by Lacy, especially when the drug used is for regulating cholesterol or lipid metabolism, since structured triglycerides have advantages relating to cholesterol and atherosclerosis and other clinical advantages as taught by Babayan, Bistraian and Hyltander respectively.

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant's arguments center around 'structured lipid'. These arguments have been extensively addressed before in paper No. 25. In essence, according to applicant, capric and/or caprylic triglycerides taught by Lacy are not structured lipids. These arguments are not found to be persuasive. Appellant's statement on page 3 of the specification is as follows: "Representative structured lipids include, but not limited to, caprylic/capric/lauric triglycerides, e.g., Captex 350TM (Abitec) and caprylic/capric/linoleic triglycerides, e.g., Captex 810 series (Abitec) and Miglycol 818 (creanova), and in general, include those lipids containing saturated medium and long

chain fatty acids esterified to the same glycerol molecule". Lacy on col. 9, lines 20-28 teaches several triglycerides under the trade names Myglycol and Captex and these come under the broad and vague definition given by applicant for a 'structured lipid'. It would appear that Lacy's teachings do not exclude structured lipids. Furthermore, the examiner cites the references of Chavkin (5,753,255), which teaches capric triglyceride as a structured lipid, and that of Kikuchi (5,506,230) MCTs as structured lipids are cited as interest (note col. 1, line 58 through col. 2, line 9 of Chavkin; col. 2, lines 24-34 of Kikuchi). The examiner points out that the claim language is given the broadest reasonable interpretation (see MPEP 2182). It would appear that in the art that the term, 'structured lipids' is given different interpretation and therefore, the interpretation given the references of Chavkin, and Kikuchi is still pertinent since instant claim 1 does not recite the specific lipids which applicant considers as structured lipids. With regard to arguments based on the lipids recited in claims 4 and 5, as discussed below, appellant has not shown any unexpected results by using specific triglycerides.


Appellant argues that instant claims now recite 'consisting of' and therefore, excludes the surfactants. Applicant further argues based on teachings of Lacy on col. 3, lines 41-42 that instant invention does not exhibit or demonstrate the property of 'not substantially inhibiting the lipolysis of the oil. These arguments are not found to be persuasive since as pointed out before, instant specification clearly indicates that surfactants can be added (see example 1 in instant specification); in fact, it would appear from the comparison between figure 1 and figure 2, the plasma concentrations of fenofibrate are higher in the presence of surfactant than without it. Applicant has not

shown any unexpected results by not including the surfactant as suggested by Lacy as argued.

Appellant argues that Babayan, Bistran and Hyltander do not disclose fibrates and the solubility of fibrates in structured lipids. According to appellant, these references teach the use of structured lipids in dietary supplements for nutritional purposes. This argument is not found to be persuasive since these references, which teach the advantages of using structured lipids; when the goal is to regulate cholesterol levels, one of ordinary skill in the art would be motivated to use the structured lipids as solvents taken together with the teachings of Lacy.

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,


Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

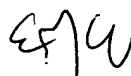
GSK
November 26, 2003

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